

EXHIBIT 75

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: Bair Hugger Forced Air Warming
Products Liability Litigation

MDL No. 2666
(JNE/DTS)

This Document Relates to All Actions

**AFFIDAVIT OF DR. WILLIAM R.
JARVIS**

STATE OF SOUTH CAROLINA)
) ss.
COUNTY OF BEAUFORT)

I, William R. Jarvis, M.D., being first duly sworn under oath, state and attest as follows:

1. This Affidavit is prepared to summarize my expert opinions with respect to 3M's argument that the "Jeans Study"¹ confounded the McGovern Study.²
2. It is my opinion, held to a reasonable degree of medical and scientific certainty, that the Jeans Study does not "suggest" that MSSA screening confounded the McGovern study.
3. I offer the following observations and opinions, each of which I hold to a reasonable degree of medical and scientific certainty:
 - a. The Jeans Study evaluated a before/after study intervention assessing the impact of screening for Methicillin-susceptible *Staphylococcus aureus* (MSSA) and decolonizing with Octenisan

¹ Jeans E, Holleyman R, Tate D, Reed M, Malviya A. *Methicillin sensitive Staphylococcus aureus screening and decolonization in elective hip and knee arthroplasty*. J INFECT. 2018;77:405-409.

² McGovern, PD et. al., *Forced-air warming and ultra-clean ventilation do not mix*, J Bone Joint Surg Br. 2011;93-B:1537-44.

bathing for 5 days before surgery and intra-nasal Bactroban for 5 days before and after the surgery on total hip arthroplasty (THA) and total knee arthroplasty (TKA) surgical site infections (SSIs) (both superficial and deep). This is not a randomized controlled study.

- b. First, the Jeans Study data set is not identical to the McGovern Study data set. The Jeans Study covers the period 2007 through 2014, whereas the McGovern Study covers the period July 1, 2008 through December 2010. Thus, the authors are not comparing the same patients over the same time period. Since the pre-operative screening did not exist before 2010, we have no idea what the MSSA-colonization rate of TKA and THA patients was in the pre-2010 period. Furthermore, “all patients attending for elective arthroplasty” were given the Octenisan bodywash (not just the MSSA-colonized patients). Only the MSSA-colonized patients were given the intranasal Bactroban.
- c. Second, Octenisan has not been a widely used or successful agent for decolonizing MSSA-colonized patients or specifically preventing THA or TKA MSSA-SSIs;
- d. Third, the Jeans Study authors did not do any type of testing after the intervention (Bactroban and Octenisan) and before the THA/TKA procedure to document or confirm whether the intervention eradicated the MSSA-colonization in those who were nasal/groin-MSSA-positive;
- e. Fourth, despite the MSSA screening program, 23 MSSA-SSIs still occurred in the Jeans Study (and even more SSIs occurred caused by other organisms);
- f. Fifth, with the use of the Bair Hugger in THA/TKA procedures, all organisms --not just MSSA or methicillin-resistant *S. aureus* (MRSA) or methicillin-resistant *S. epidermidis* (MRSE) or methicillin-susceptible *S. epidermidis* (MSSE)--would be potentially blown in to the operative field. The Jeans Study had 108 SSIs caused by bacteria that were not MSSA. In fact, the non-MSSA SSI rate increased from 1.14 in the pre-screening group to 1.16 in the post-screening group;
- g. Sixth, the rate of TKA MSSA-SSIs did not significantly decrease despite the use of Octenisan and Bactroban;

- h. Seventh, the rate of non-MSSA TKA SSIs actually increased from 0.61 in the pre-screening group to 1.07 in the post-screening group. This difference almost reaches statistical significance, suggesting that this intervention may actually result in increased THA/TKA SSIs with non-MSSA organisms;
- i. Eighth, the Jeans Study reported THA/TKA SSIs. There was no stratification of the data by superficial or deep SSIs. Such an analysis should have been done in the Jeans Study. McGovern, in contrast, focused only on deep SSIs. The Jeans and McGovern Studies, then, both analyze different data sets, different time periods, different surveillance methods and measure different outcomes. It is therefore inappropriate to “suggest” that the MSSA screening confounded McGovern;
- j. Indeed, in 2017, the United Kingdom’s National Institute for Health and Care Excellence (NICE) conducted an evaluation of the published literature on the evidence for effectiveness of nasal decontamination in prevention of superficial, deep, and organ space SSIs (<https://www.nice.org.uk/guidance/ng125/documents/evidence-review>). In the evaluation of nasal decolonization in combination with body wash using alternative interventions such as Octenisan, they concluded: “No studies of relevant study design were identified which examined the effectiveness ofoctenisan nasal gel”. No studies were found to document the efficacy of Octenisan in the reduction of SSIs in general, or TKA/THA procedures in particular.
- k. Moreover, in a Pubmed search of Octenisan decolonization to reduce SSIs (of MSSA, MRSA or any other bacterial pathogen) on May 13, 2019, the Jeans Study is the only study identified. There are no other data to confirm that use of Octenisan body washes with intranasal Bactroban reduces any SSIs, much less TKA/THA SSIs.
- l. It does not appear as if the surveillance period (follow-up after the TKA/THA procedure) is the same in the McGovern and Jeans Studies. In the McGovern study, it is stated in the methods that “only infections presenting within 60 days of surgery were included”. In contrast, the Jeans Study states that “data from Public Health England surgical site infection surveillance service were cross referenced with this centrally gathered data...and that they used Public Health England’s published standard on superficial, deep and organ space infection identified.” The Public Health England “Protocol for the Surveillance of Surgical site Infection”

indicates that “If an implant is inserted and left in the surgical site than an infection may meet the definition of SSI for up to 1 year after the operation”.

(https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/633775/surgical_site_infections_protocol_version_6.pdf). Thus, the duration of surveillance after the THA/TKA in the Jeans Study (one year) was significantly longer than in the McGovern Study (60 days) making the two studies impossible to compare. Different surveillance methods, different interventions and different outcomes measured. More likely than not, if the McGovern Study had conducted surveillance for THA/TKA SSIs for one year rather than 60 days, that the number of SSIs would have been much larger;

- m. Ninth, even if one were to argue that an MSSA intervention would impact THA and TKA MSSA-SSIs, it should be noted that in both groups in the intervention period such MSSA-SSIs still occurred—they were *not* eradicated by such treatment. In fact, the authors of the Jeans Study admit that “improvement in infection rates could have been [due] to other factors than MSSA screening.” Dr. Borak agreed in his deposition in February 2019, and further agreed that it is possible that the use of Bair Hugger may have, in fact, confounded Jeans (Borak Feb. 2019 Dep. at 35:13; 36:10-13);
- n. Most importantly, Reed et al. continue to cite the McGovern et al. paper/results. It stands to reason, that if Reed et al. thought their results in McGovern et al. were unreliable or otherwise explained or undermined by subsequent research, Reed et al. would not have cited McGovern et al. as evidence that FAW systems, including the Bair Hugger, have been associated with a 3.8 relative risk of developing deep joint infections. However, Reed et al. did in fact cite his work in McGovern et al. in the 2019 paper he wrote with Jain et al.³, which states:
 - “airborne particles carrying contaminating microorganisms are responsible for 98% of surgical site infections.” Furthermore, they indicate that the “main problem with [Laminar Air Flow] is turbulence caused by physical barriers

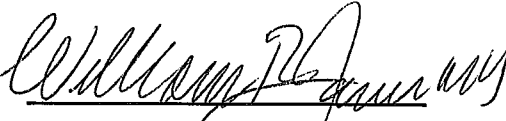
³Jain S and Reed M. *Laminar air flow handling systems in the operating room*. SURGICAL INFECTION 2019;20:1-8.

and heat sources obstructing and diverting contaminated air flow currents toward the incision.”

- Last, Reed et al. and Jain et al. point out that “forced air warmers could be considered detrimental to effective laminar air flow and this has been recognized by the National Institute for Health and Care Evidence guidelines on peri-operative warming in orthopedic surgery” and the authors recommended “a resistive heating mattress or blanket [instead] of a forced air warmer device.”

FURTHER THIS AFFIANT SAYETH NAUGHT.

Dated: May 14, 2019



William R. Jarvis, M.D.

Notarized:

JURAT STATEMENT

Sworn and subscribed before me

On this 14th day of May, 2019


Notary Public for South Carolina

OFFICIAL SEAL
JODI-ANN DONNELLY
Notary Public for South Carolina
My Commission Expires Feb. 24, 2024